

EPIDURAL THERMAL POSTERIOR ANNULOPLASTY

The present application is a nonprovisional of U.S. Provisional Patent Application Serial Number 60/393,448 filed July 3, 2002, and a continuation-in-part of
5 U.S. Patent Application Serial Number 09/832,642 filed April 10, 2001, which is a nonprovisional of U.S. Provisional Patent Application Serial Number 60/238,803, filed October 6, 2000. The present application is based on and claims priority from these applications, the disclosures of which are hereby incorporated herein by reference.

10 BACKGROUND OF INVENTION

The present invention is directed to a treatment for injured or degenerated intervertebral discs using a ribbon epidural thermal posterior annuloplasty of the present invention. Specifically, the present invention is a method and apparatus for strengthening an injured or degenerated intervertebral disc and relieving pain. The
15 treatment may allow a spine surgeon to avoid a discectomy and removal of the nucleus pulposus during laminectomy operations and may reduce postoperative discogenic pain.

As shown in FIG. 1, each intervertebral disc 10 is a cushion-like pad with top and bottom endplates adjoining the bone surfaces on each adjacent vertebral body
20 20. As shown in FIG. 2, each disc has an inner sphere, the nucleus pulposus 30, which acts as a cushion for compressive stress. Around the nucleus pulposus is an outer collar of approximately 12 concentric rings, the annulus fibrosis 40, which limits the expansion of the nucleus pulposus when the spine is compressed. The rings of the annulus fibrosis also bind the successive vertebrae together, resist torsion of the spine,
25 and assist the nucleus pulposus in absorbing compressive forces.

The grains of collagen fibers in adjacent rings of the annulus fibrosis 40 run in different directions so that the grains cross like an X. This arrangement of the collagen layers allows the spine to withstand twisting, shear forces.

FIG. 2 shows an exemplary injury to an intervertebral disc. A herniated or prolapsed disc is commonly called a "slipped disc." Severe or sudden trauma to the spine or nontraumatic pathology such as degenerative spine disease may cause a bulge, rupture, degeneration, or other area of injury ("injury") 50 in one or more intervertebral discs. The annulus fibrosis 40 is thinnest posteriorly in the general direction of the spinous process 60, so the nucleus pulposus 30 usually herniates in that direction. The injury usually precedes posterolaterally instead of directly posteriorly because the posterior longitudinal ligament strengthens the annulus fibrosis at the posterior sagittal midline of the annulus. The terms "posterior" and "posteriorly" mean the general posterior and posterolateral aspects of the disc as distinguished from the anterior aspects of the disc. The posterior aspect of the annulus fibrosis is also the location of vulnerable nerve tissues, including but not limited to the cauda equina 70 and spinal nerve roots 80.

A posterior injury of the nucleus pulposus often impinges on the spinal nerve roots 80 exiting the spinal canal 90. The resulting pressure on these nerve roots often leads to pain and/or numbness in the lower extremities. Injured intervertebral discs are treated with bed rest, physical therapy, modified activities, and painkillers over time. If these treatments are ineffective, the injured and usually protruding disc is often surgically removed.

Current treatments offer only limited success in avoiding surgical removal of injured intervertebral discs that do not heal themselves over time. A few treatments are adopted for use on an intervertebral disc from broad methods to shrink collagen in various other parts of the body. Several treatments attempt to reduce discogenic pain.

Several exemplary prior art references disclose using heat to shrink collagen. U.S. Patent Nos. 5,374,265 and 5,484,432 to Sand (the "Sand references") are directed to methods for shrinking collagen with an infrared laser. The collagen shrinkage in the Sand references is generally accomplished in an ophthalmological context. Laser light that is optimally absorbed by collagen tissue is applied to a corneal stoma resulting in collagen shrinkage and reshaping of the cornea for vision correction. Although the Sand method generally applies to shrinkage of collagen, it only

contemplates applying relatively small amounts of energy to delicate eye tissue. No provision is made for protecting vulnerable tissue near collagen in other parts of the body. The amount of energy needed to shrink collagen in synovial joints or the spine is greater than the amount needed for eye tissue and may damage vulnerable tissue near
5 the collagen being treated.

U.S. Patent Nos. 5,458,596 and 5,569,242 to Lax et al. (the "Lax references") are directed to broad methods and apparatuses for controlled contraction of soft tissue. The Lax references disclose the application of radio frequency energy through an electrode to tissue containing collagen. Such an application of energy as
10 envisioned by the Lax references to an intervertebral disc would damage vulnerable tissues near the application site. The Lax references do not disclose the use of energy other than radio frequency. The suggested shapes of the multiple embodiments of the Lax electrode are all problematic. The embodiments shown in FIGS. 1 and 4 are elongated electrodes, the embodiment shown in FIGS. 2 and 3 has a distal end with all
15 the edges being radiused, the embodiment shown in FIG. 10 has channels or gaps, the embodiment shown in FIG. 14 is positioned within a sharp wedge shaped cannula, and the embodiment shown in FIG. 18 has a roller element with projections. None of the embodiments disclosed in the Lax et al. reference are suitable for separating and insulating the nerve roots, dura, and thecal sacs of the spinal canal on one side of the
20 instrument from the energy delivery occurring at the surface of the intervertebral disc on another side of the instrument. For example, the distal end with all the edges being radiused (FIGS. 2 and 3) is not shaped for gentle lifting, but would abruptly push its presence into tight spaces with its leading radiused edge. Another example is the sharp wedge shaped cannula in which an electrode is positioned (FIG. 14). The cannula's
25 shape is pointed such that it would tend to cut or poke its way into position. Although FIG. 23 shows one embodiment being used on a herniated disc, it does not show the device inserted into the tight epidural space and, in fact tends to show the device moving toward the anterior of the annulus fibrosis.

U.S. Patent No. 5,954,716 to Sharkey et al. (the "Sharkey '716 reference")
30 is directed to a method and device for modifying the length of a ligament. In the

Sharkey '716 reference, radio frequency energy is applied to one ligament in a set of opposing ligaments. Only radio frequency energy is disclosed. The radio frequency energy shrinks one ligament, restoring equal length and a balance of function to the set of opposing ligaments. Although the Sharkey '716 treatment uses radio frequency energy to shrink a ligament, it would not work on an intervertebral disc because an intervertebral disc is surrounded by vulnerable tissues. Because intervertebral discs lie close to the spinal canal and spinal nerve roots, application without thermal protection of radio frequency energy suitable for shrinking a ligament might harm vulnerable nerve tissues.

Heating an intervertebral disc for relief of discogenic pain is disclosed in U.S. Patent Nos. 5,433,739 and 5,571,147 to Sluijter et al. (the "Sluijter references"). In the Sluijter references, probes are inserted into an intervertebral disc by puncturing the annulus fibrosis. Radio frequency or direct current energy is delivered through probes to heat the nucleus pulposus of a disc to approximately 60° C to 70° C. The heat travels to the outer perimeter of the disc being treated so that the entire disc is heated. The applied heat relieves back pain by denervating fine nerve endings in the disc. Although the probes of the Sluijter references may relieve back pain, the Sluijter probes invade the disc and are not intended to shrink collagen or repair a bulging, ruptured, or injured intervertebral disc. Since the entire disc is heated to approximately 60° C to 70° C, the heat may harm vulnerable tissues near the disc and have other thermally detrimental side effects. Some recent studies have shown that the amount of thermal energy provided to the posterior annulus by the IDET procedure is insufficient to cause either shrinkage/strengthening of the posterior annulus or ablation of the pain-sensing posterior annular nerve endings.

Several prior art references disclose methods for applying energy to the interior of an intervertebral disc by invading the disc with a needle or catheter. For example, U.S. Patent No. 5,865,833 to Daikuzono is directed to a device for laser treatment. The Daikuzono device is for a discectomy procedure and for removal of intervertebral disc tissue, not to avoid a discectomy or to preserve disc tissue or ablate posterior annulus pain-sensing nerve endings. The Daikuzono method uses a hollow

needle that is advanced into the center of an intervertebral disc, and then disc tissue is vaporized with laser energy and the vapor removed through the hollow needle. The hollow needle invasively punctures the disc.

U.S. Patent Nos. 6,007,570, 6,073,051, 6,095,149, and 6,122,549 to

5 Sharkey et al. (the "Sharkey references") are directed to methods for treating an intervertebral disc and to devices with tip portions for performing various functions on a disc. Externally guidable catheters having one lumen or several lumina puncture the annulus fibrosis of an intervertebral disc and are inserted into the nucleus pulposus at the center of the disc. Functional tips on the distal ends of the catheters add or remove
10 material or deliver energy. The Sharkey references also disclose injecting a sealant into fissures in the annulus fibrosis. The methods and devices of the Sharkey references have the advantage of treating an intervertebral disc from the inside, thereby using the annulus fibrosis of a disc as thermal insulation from the spinal canal. The Sharkey methods and devices, however, have the disadvantage of not being able to reach many
15 types of bulges, ruptures, or areas of injury in or near the outer layers of the annulus fibrosis. Further, because they puncture the disc, the Sharkey catheters are invasive and larger puncture holes are needed in order to use larger functional tips. The Sharkey methods and devices do not provide a noninvasive external approach to disc repair, and require maneuvering a catheter inside an intervertebral disc. They also do
20 not ablate nerve endings in the posterior annulus and do not shrink/strengthen the posterior annulus.

Known prior art methods for treating an injured intervertebral disc are invasive to the disc, do not shrink/strengthen the posterior annulus, do not ablate the pain-sensing nerve endings in the posterior annulus, and may be thermally unsafe to
25 vulnerable tissues around the spine.

BRIEF SUMMARY OF THE INVENTION

The present invention provides a method and apparatus for shrinking and strengthening the cartilaginous or collagenous material ("collagen") near an injury in the annulus fibrosis or the nucleus pulposus of one or more intervertebral discs. The
5 present invention may allow a spine surgeon to avoid a discectomy and removal of the nucleus pulposus during a laminectomy operation.

The present invention's epidural and extradiscal approach to repairing a disc prevents the invasion of a disc with a needle or catheter. Needle and catheter methods puncture the intervertebral disc being treated, thereby exacerbating the very
10 condition sought to be cured or may introduce infection into the nerve space.

The present invention may eliminate or greatly reduce discogenic pain by thermally destroying nerve endings that transmit pain sensation from the posterior annulus. The surface area of the posterior annulus that can be treated for the reduction of discogenic pain is not limited as in prior art methods that deliver energy from a device
15 inside the disc.

During thermal treatment by the present invention, vulnerable tissues near a disc undergoing treatment may be thermally insulated or cooled and/or displaced away from the thermal energy and thereby protected from potentially destructive heat. Laser embodiments of the present invention may achieve thermocoagulation of disc
20 tissue by short laser bursts that confine heating to the disc. This thermal confinement combined with posterior displacement of neural structures may protect these vulnerable tissues near a disc without requiring insulation or cooling of the vulnerable tissues.

The present invention's strengthening of collagen may result in the reduction of future incidents of disc herniation, reduction of spinal nerve-root
25 impingement, and reduction of discogenic pain arising from nerve endings in posterior annulus.

The present invention is directed to an apparatus for treating at least one intervertebral disc. Preferably, the apparatus includes an expandable and contractible energy application head having an energy application region and a tissue protecting
30 region. A distance is defined between the energy application region and the tissue

protecting region. The distance is variable to protect tissue associated with the intervertebral disc. In one preferred embodiment, the energy application head has smooth, rounded edges, a domed center section, and the edges are sloped to the domed center section such that the energy application head has a wedge-shaped head geometry. In another preferred embodiment, the energy application head is a ribbon-like energy application head.

The present invention also includes a method for thermally treating an injured intervertebral disc while thermally protecting vulnerable tissues.

The foregoing and other objectives, features, and advantages of the invention will be more readily understood upon consideration of the following detailed description of the invention, taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

FIG. 1 is a posterolateral view of two adjacent lumbar vertebrae.

FIG. 2 is a transverse cross-section through the spine showing a ruptured intervertebral disc, the spinal canal and cauda equina, and the bony processes of a vertebra.

FIG. 3 is a flowchart of a preferred method of the present invention for thermal treatment of a bulging, ruptured, or injured intervertebral disc.

FIG. 4 is a transverse cross-section through a spine with an exemplary disc refurbisher head positioned near the posterior annulus.

FIG. 5 is a top view of an exemplary head and part of an exemplary control member of one preferred embodiment of the disc refurbisher of the present invention.

FIG. 6 is a side view of the exemplary head and a cut-away view of part of the exemplary control member of FIG. 5.

FIG. 7 is a side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing an expanded head shape.

FIG. 8 is a side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing a contracted head shape.

FIG. 9 is a side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing a flat energy application region.

5 FIG. 10 is a side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing a concave energy application region.

10 FIG. 11 is a side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing a convex energy application region.

FIG. 12 is a side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing a malleable energy application region.

15 FIG. 13 is a side and partial cut-away view of a section of an exemplary control member of one preferred embodiment of the present invention showing optional operational members.

FIG. 14 is a cross-sectional side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing control members operationally connected to a head.

20 FIG. 15 is a cross-sectional side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing an integrated defocused laser as an energy applicator.

25 FIG. 16 is a cross-sectional side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing an external defocused laser as an energy applicator.

FIG. 17 is a cross-sectional side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing a lens as an energy applicator.

FIG. 18 is a cross-sectional side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing electrodes as energy applicators.

5 FIG. 19 is a cross-sectional side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing a wire as an energy applicator.

FIG. 20 is a cross-sectional side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing a light bulb as an energy applicator.

10 FIG. 21 is a cross-sectional side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing a resistive heating element as an energy applicator.

FIG. 22 is a cross-sectional side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing an ultrasonic transducer as an energy applicator.

FIG. 23 is a cross-sectional side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing an integrated defocused laser for slowly applying thermal energy.

20 FIG. 24 is a cross-sectional side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing an external defocused laser for slowly applying thermal energy.

FIG. 25 is a cross-sectional side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing an integrated collimated laser for applying thermally confined energy.

25 FIG. 26 is a cross-sectional side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing an external collimated laser for applying thermally confined energy.

FIG. 27 is a cross-sectional side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing optional optical devices for visualizing a treatment area.

FIG. 28 is a cross-sectional side view of an exemplary head of one preferred embodiment of the disc refurbisher of the present invention showing an exemplary instrument for performing a physical measurement.

5 FIG. 29 is a cross-sectional side view of an exemplary ribbon head of one preferred embodiment of the disc refurbisher of the present invention, the exemplary ribbon head shown in an expanded state.

FIG. 30 is a cross-sectional side view of an exemplary ribbon head of one preferred embodiment of the disc refurbisher of the present invention, the exemplary ribbon head shown in a contracted state.

10 FIG. 31 is a perspective view of the exemplary ribbon head in the contracted state of FIG. 30.

FIG. 32 is a cross-sectional side view of an exemplary ribbon head with a rounded tip of one preferred embodiment of the disc refurbisher of the present invention, the exemplary ribbon head shown in an expanded state.

15 FIG. 33 is a transverse cross-section through a spine with an exemplary ribbon head shown in a contracted state and positioned in the epidural space on the posterior annulus.

20 FIG. 34 is a transverse cross-section through a spine with an exemplary ribbon head shown in an expanded state and positioned in the epidural space on the posterior annulus.

DETAILED DESCRIPTION OF THE INVENTION

Epidural thermal posterior annuloplasty is a method for shrinking and strengthening the collagen at an injury in the annulus fibrosis of the nucleus pulposus of one or more intervertebral discs. This method of the present invention differs from
5 previous methods by treating one or more intervertebral discs from an epidural, extradiscal approach while protecting vulnerable tissue near the disc. Central to the method of the present invention is a disc refurbisher device having an energy source that heats the injured tissue without vaporizing it. The heating may cause shrinkage of the collagen resulting in a stronger, tighter intervertebral disc and desirable destruction
10 of microscopic pain-causing nerve endings in the intervertebral disc being treated. The intervertebral disc is not physically invaded, and tissues surrounding the disc remain safe.

In one preferred embodiment, the disc refurbisher includes an energy application head having an energy application region and a tissue protecting region.
15 The tissue protecting region may be created by varying the thickness of the head by expanding and/or contracting a distance between the energy application region and the tissue protecting region and that distance is variable to protect vulnerable tissues associated with intervertebral disc. The energy application head preferably has a contracted state (FIGS. 8, 30, and 31) in which the distance is a minimum distance, an
20 expanded state (FIGS. 7 and 29) in which the distance is a protecting distance greater than the minimum distance, and means for varying the distance between the minimum distance and the protecting distance. The distance may be varied in proportion to the amount of energy being delivered to the intervertebral disc. The distance may be varied automatically or manually. The distance may be varied using mechanical means, by
25 using an inflatable top portion that expands under air or liquid pressure, or by other means for varying the distance. One example of a disc refurbisher having an energy application head with variable thickness is the embodiment shown in FIGS. 7 and 8. Another example of a disc refurbisher having an energy application head with variable thickness is the embodiment is shown in FIGS. 29-31. Still another example of a disc

refurbisher having an energy application head with variable thickness is the embodiment is shown in FIG. 32.

Description of Preferred Apparatuses of the Present Invention

5 A preferred apparatus embodiment of the present invention is a disc refurbisher that may be used intraoperatively, but not necessarily for percutaneous spine surgery. A disc refurbisher has a shape for approaching an intervertebral disc epidurally. In one preferred embodiment, the disc refurbisher has an energy delivery system for treating at least one intervertebral disc. In an alternate preferred
10 embodiment, the disc refurbisher has additional thermal protection features for safeguarding tissues that surround an intervertebral disc. In yet another alternate preferred embodiment, the disc refurbisher is a flexible ribbon-like epidural thermal posterior annuloplasty device.

15 Shape and Physical Geometry

 FIGS. 5 and 6 show a first preferred energy application head ("head") 180 of the disc refurbisher. This embodiment is preferably shaped so that the approach to an injured intervertebral disc may be epidural. To approach epidurally, the surface of the exemplary head 180 of the instrument is preferably smoothly contoured to glide over
20 the posterior annulus and reach the injury site without snagging or tearing the nearby nerve roots, epidural blood vessels, dura, and thecal sac. The smooth, rounded edges 210 of the anterior portion of the head 180 lift and displace the dura to epidurally gain access to the site of injury at the annulus fibrosis and reduce the thermal effect on the dura and neural structures. The head is preferably thinner at its smooth rounded edges
25 210 than at its exemplary domed center 220, allowing easy insertion between tissue layers and separation of tissues as the instrument is advanced to the injury site or moved from side to side. The shape facilitates treating adjacent discs by manipulating the disc refurbisher in the epidural space.

A wedge-shaped cross-sectional or longitudinal geometry of an exemplary head, such as the head shown in FIGS. 5 and 6, separates and thereby insulates the nerve roots, dura, and thecal sacs of the spinal canal on one side of the instrument from the energy delivery occurring at the surface of the intervertebral disc on another side of the instrument. The smooth, rounded edges 210 of the anterior portion of the exemplary head are relatively thin and slope to a relatively thick region under the exemplary domed center 220 creating a wedge-shaped head geometry.

The wedge-shaped exemplary head has a maximum wedge thickness that may automatically lift vulnerable tissues a calculated safe distance away from a site of energy application as the instrument is moved. A calculated safe distance may be proportional to the amount and duration of energy being applied or proportional to temperatures induced in the disc. In one variation shown in FIGS. 7 and 8, the maximum wedge thickness of a head is variable and automatically expands 300 or contracts 310 in proportion to the amount of energy being delivered. The variation in thickness may be accomplished mechanically or by using an inflatable top portion that expands under air or liquid pressure.

In FIGS. 9-12, the energy application regions of preferred head embodiments may be flat 320, concave 330, convex 340, or malleable 350. Initially, an embodiment with a concave energy application region may be used to approximate the contour of a bulging area of disc, followed by an embodiment with a flat energy application region to impart a finished surface to the shrunken and tightened collagen. Each embodiment is operationally connected to at least one controlling member 190.

A head embodiment may have a diameter of approximately five millimeters, but a wider head could be used for tissue shielding or a wider application of energy. Alternately, a set of disc refurbishers may have heads of various useful shapes and sizes. Still another alternative disc refurbisher may have a head that varies in size using mechanical means.

In FIGS. 5 and 6, an operational steering and controlling member ("control member" 190) such as an exemplary longitudinal shaft member may be attached to a

disc refurbisher head 180 at an angle from the plane of the head of between 0° and 180°, shown as 25°. Alternately, the control member 190 may be rotatably connected to the head. The control member 190 may be stiff, flexible, malleable, or articulated to provide physical control of disc refurbisher movement. In FIG. 13, a portion of a control member 190 is shown as optionally containing operational members, such as at least one wire 360, fiber-optic strand 370, hollow tube 380, or radio control device 390. The hollow tube 380 or lumen may allow instruments such as micro-forceps, biopsy samplers, and aspirators to be inserted through the disc refurbisher to the site of treatment. Matter and bodily tissues, such as blood, irrigation fluid, vascular lesion tissue, sequestered disc fragments, and synovial cyst tissue may be removed through the hollow tube 380 in the disc refurbisher. Several lumina may be used to provide irrigation to the site of treatment. The control member 190 may also contain a moving mechanical link, such as a rotating inner shaft 400 or an oscillating inner member. Alternately, as shown in FIG. 14, control members 410 may be one or more wires, radio control mechanisms, beams of light, or any other control mechanism. One or more control members 410 may be attached in various useful configurations and at various useful angles.

FIGS. 29-31 show an exemplary alternative ribbon head 800 of one preferred embodiment of the disc refurbisher of the present invention. FIG. 29 shows the exemplary ribbon head in an expanded state and FIGS. 30-31 show the exemplary ribbon head in a contracted state. The ribbon head 800 is preferably long and flexible. This shape allows simultaneous treatment of a large area of the posterior annulus. Further, the treatment may occur in an automated fashion. For example, once positioned, the ribbon head 800 may be left in place across the posterior annulus to treat a large area. This can be compared to the previously discussed embodiments that must be manipulated and/or "painted" on posterior annular surface to treat a large area.

It should be noted that the terms "ribbon" and "ribbon-like" are meant to describe an elongated, relatively flat, flexible construction. Although the ribbon head is discussed in terms of an expandable and contractible embodiment, an alternative embodiment a ribbon head does not have a variable thickness. The flexible nature may

have enough stiffness to allow insertion into appropriate areas. In the shown embodiment, the bottom surface is an energy application region and the top surface is a tissue protecting region, but this could be reversed. The tip shown in FIG. 31 could also be tapered inwards from both sides to form a rounded point and still maintain a wedge-shaped cross-section. Unlike many of the prior art devices, the present invention is relatively flat, at least in the contracted state. One advantage to the relatively flat shape is that it can be inserted into relatively tight spaces such as the epidural space.

In one preferred embodiment, the ribbon head 800 is layered in that it includes a bottom layer 802, an optional middle layer 804, and a top layer 806.

Preferably, these layers are internal and the exterior surface is substantially free of structure that could snag or tear tissue. In one preferred embodiment, the bottom layer 802 may contain the energy applicators and/or devices for measuring and monitoring. The exterior surface of the bottom layer 802 forms the energy application region. An optional feature that may be present in the bottom layer is an ultrasound transducer to visualize the underlying posterior annulus. The middle layer 804 preferably consists of thermal insulation that might extend over the sides and end of the device to provide better insulating coverage. This layer of thermal insulation is optional as thermal insulation may be achieved through the use of the top layer 804 alone. FIG. 32 shows an embodiment of a ribbon head 800' without the middle layer. The top layer 806 serves to deflect the overlying dural sac and nerve roots to protect them from the effects of the thermal treatment. In one preferred embodiment, the top layer 806 may be expandable. For example, the top layer 806 might be expandable using mechanical mechanisms, pneumatic mechanisms, or hydraulic mechanisms. The top layer may also contain sensing and/or monitoring devices such as a temperature thermo-couple. In an alternative preferred embodiment, the top layer and/or middle layer may provide insulation by changing thermal and/or insulating properties either alone or in combination with expansion and contraction. The change in properties could be accomplished by electrical, chemical, or mechanical properties of the layer or liquid inserted into the layer. In an embodiment in which the ribbon head is not expandable and contractible, the top layer 806 may be omitted.

The tip of the ribbon head 800 may be wedged shaped to separate and thereby insulate the nerve roots, dura, and thecal sacs of the spinal canal on one side of the instrument from the energy delivery occurring at the surface of the intervertebral disc on another side of the instrument. The leading edge is preferably smooth and rounded to protect tissue and nerval structures during insertion. The embodiment shown in FIG. 32 has an alternative, radiused tip. The radiused tip may also be thermally insulated.

As discussed with the alternative embodiments, the ribbon head may have many variations. For example, the energy application region may be flat 320, concave 330, convex 340, or malleable 350. The ribbon head is preferably operationally connected to at least one controlling member 190. The dimensions shown are meant to be exemplary and are primarily for purposes of illustration. In one preferred embodiment, the thickness of a contracted ribbon head is approximately 1-3 mm and the thickness of an expanded ribbon head is approximately 5-10 mm. Depending on the application (e.g. the size of the patient), the ribbon head would range from 30 mm to 80 mm in length. Ribbon heads may come in a variety of useful shapes and sizes. The control member 190 may have variations such as those discussed in connection with other embodiments. Optional monitoring capabilities may also be included to monitor the target tissue temperature as well as the temperature of the tissue that require protection. Further, once in place, the device could be checked with an x-ray (or other monitoring equipment) prior to treatment.

Energy Application

As shown in FIG. 6, a disc refurbisher embodiment of the present invention may deliver energy to an intervertebral disc from an energy applicator on an energy application region, shown as the bottom side 500, of the instrument's head 180. Surfaces other than the shown bottom side could be used as the energy application region in other embodiments. Energy applicators may be positioned on, may consist of, or may deliver energy through an energy application region depending on the type of

energy applicator being used. As shown in FIGS. 15-22, energy applicators may include one or more lasers 420, fiber-optic strands 430, lenses 440, electrodes 450, wires 460, light bulbs 470, heating elements 480, and ultrasound transducers 490. A disc refurbisher may have more than one energy-delivering side and each energy-delivering side may have more than one energy application region.

The energy applicator may be supplied with energy from a source external to the head, for example laser energy transmitted by optical fibers from an external laser to the head. Alternately, the energy applicator may generate or convert energy within the head, for example electric current from an external source carried to a resistive heating element within the head. If energy is supplied to the head, transmission of energy through a control member may be through any energy transmission means, such as wire, lumen, thermal conductor, or fiber-optic strand. In FIG. 6, an exemplary fiber-optic bundle 510 fans out 520 into a useful pattern at the energy application region, shown as the flat bottom 500 of the head.

The disc refurbisher may deliver electromagnetic energy, including but not limited to radio waves, microwaves, infrared light, visible light, and ultraviolet light. The electromagnetic energy may be in incoherent or laser form. The energy in laser form may be collimated or defocused. The energy delivered to a disc may also be electric current, ultrasound waves, or thermal energy from a heating element.

One exemplary preferred embodiment uses laser energy. The interaction of laser energy with the collagen of an intervertebral disc has photothermal, photomechanical, and photochemical components. The present invention takes advantage of all three effects.

Photothermally, photons absorbed by a disc heat the disc and thermally coagulate the collagen ("thermocoagulation"). Thermocoagulation may be achieved by applying energy with a continuous or long-pulse laser using microsecond or millisecond pulses. FIGS. 23 and 24 show preferred embodiments of a disc refurbisher in which defocused lasers are used to provide a relatively slow, areawide application of heat. FIG. 23 shows an integrated defocused laser 530. FIG. 24 shows an external

defocused laser 535 that may use a fiber-optic bundle in the transmission of defocused energy. Since lasers are monochromatic, wavelengths may be selected that would efficiently match the peak absorption range of collagen. To optimize the relatively slow application of heat using a defocused laser embodiment, a photosensitive chemical reagent that would enhance or modify the absorption of selected laser energy could be painted or sprayed onto the target and exposed to the laser output.

Alternately, laser energy for thermocoagulation may be collimated. FIGS. 25 and 26 show preferred embodiments in which the energy applicator of a preferred disc refurbisher is a collimated laser. In FIG. 25, an integrated laser 540 generates the collimated laser energy. In FIG. 26, an external laser 550 generates collimated laser energy that is focused into optical fibers 555 for delivery to the treatment site and optionally focused to very small areas by at least one lens 560. The laser light may be short-pulsed, which would make the delivery of relatively large amounts of energy, such as gigawatts, possible in very short time periods, such as nanoseconds. Short-pulsed laser bursts may achieve thermal confinement, the desirable rapid buildup of heat in a treatment site before thermal diffusion can dissipate the heat, preventing the heating of vulnerable tissues near the disc.

Photomechanically, the laser may be used for vaporizing undesirable tissues or spallation of the surface layer of the disc, in addition to overall thermocoagulation of the collagen. Spallation achieves surface modification by removing only superficial collagen layers. During disc surgery, at the free boundary of an air/collagen interface, collagen expands at the surface when exposed to a rapid laser pulse, and then snaps back with elastic force. The expansion creates positive pressure, but the recoil creates negative pressure. If the negative pressure exceeds the strength of the collagen, then the surface layer breaks. A thin layer of collagen is ejected. Such breaks or spall planes induced in the surface of the collagen could be used to shape a finished surface of the disc or to eject unwanted bulge material at the beginning of a disc refurbishment procedure. A vaporizing laser may be used to remove undesirable tissues, such as excess collagen, vascular lesion tissue, sequestered disc fragments, and synovial cysts.

Photochemically, the therapeutic application of energy to an intervertebral disc may cause several physiological changes. Once the delivered laser or other energy is translated into thermal energy in the collagen in or near an injury in the annulus fibrosis, a desirable microscopic breakdown of pain-causing nerve ending tissue may occur if so desired by the practitioner. The therapeutic destruction of nerve endings begins to occur when the temperature of the annulus reaches approximately 45° C. At temperatures above 60° C, changes in the cross-linked structure of the collagen near an injury in the annulus begin to occur. The thermal denaturing of the collagen protein molecules causes thermocoagulation and desirable shrinkage of the bulging, ruptured, or injured annulus fibrosis. The thermocoagulation is accompanied by a simultaneous strengthening of the annulus fibrosis.

Photochemical welding of injuries, for example tears, in the annulus fibrosis may also be accomplished by using a chemical reagent containing an adhesive photoactivated by laser light.

Thermal Protection of Vulnerable Tissues

The manner of energy delivery may forestall the need to protect vulnerable tissues, as when a pulsed laser achieves thermocoagulation with thermal confinement to the disc. In FIG. 6, when thermal protection is needed because of the type of energy applicator being used, thermally vulnerable tissues near a site of energy application to a disc may be protected by an exemplary tissue protecting region 600 of an energy application head 180. A tissue protecting region 600 may contain a thermal protector, including but not limited to at least one optional insulation layer 610, and/or an optional cooling system 620. One or more optional layers of insulation 610 or a cooling system 620 in a preferred embodiment of a disc refurbisher may thermally separate an energy applying side of a disc refurbisher head from a tissue protecting side. The tissue protecting region may also result from a disc refurbisher shape that lifts vulnerable tissues away from a site of energy application. An expandable and contractible section (such as upper layer 806 shown in FIGS. 29-30) may also provide tissue protection.

A disc refurbisher may be cooled by internal or external airflow, or by fluid or liquid pumped from a cooling reservoir such as a controlled temperature bath. As shown in FIG. 6, the cooling system of one preferred embodiment of a disc refurbisher may incorporate internal cooling tubes 620. Refrigerants may be used in the cooling tubes to provide mild or aggressive cooling. Cooling may be controlled by mechanism or computer to counteract a proportional amount of heat being generated by a disc refurbisher. Alternately, the cooling may be accomplished by at least one thermocouple in contact with the tissue protecting region of a head embodiment. The thermocouple may constitute all or part of the material surface of a tissue protecting region. As another alternative, heat-pipe technology currently used to cool state-of-the-art microprocessor chips may also be used as a preferred thermal protector. The tissue protecting side may incorporate metals such as aluminum alloys or other materials having high heat conductivity and heat-sinking properties to transfer heat to a cooling system.

A preferred embodiment of a disc refurbisher, shown in FIG. 6, has an energy delivery system, shown as a fiber-optic bundle 510 and 520, surmounted by a cooling system shown as a layer of insulation 610, cooling tubes 620, and a thermally conductive metal outer surface.

Sensors and other instruments including but not limited to thermometers, thermistors, thyristors, phosphor-coated optic fibers, and temperature-sensitive crystals may monitor temperatures at the energy application and tissue protecting regions of a disc refurbisher and adjust the energy applicators and cooling systems to maintain selected temperatures. The control of heating and cooling may be by thermostat, electronic circuit, computer, or any other mechanism able to adjust dynamically temperature.

Other Embodiments and Features

All embodiments of a disc refurbisher may be robotically manipulable. At least one robotic mechanism may be used to place a disc refurbisher at the surface of a

disc, to apply energy, and to move a disc refurbisher around the posterior annulus of a disc. A disc refurbisher under robotic control may apply computer-controlled amounts of energy in computer-controlled patterns and amounts.

5 A disc refurbisher may optionally contain at least one tube or lumen for transmitting material to and from a treatment site. A lumen may transmit a gas or fluid such as compressed air or water to the treatment site for uses including but not limited to irrigation, clearing away debris, and cooling. The lumen may also be a suction channel for vacuuming debris from the treatment site. The lumen may allow instruments such as micro-forceps, biopsy samplers, aspirators, and other surgical tools
10 to be inserted through the disc refurbisher to the site of treatment. Matter and bodily tissues, such as blood, irrigation fluid, vascular lesion tissue, sequestered disc fragments, synovial cyst tissue, and vaporized tissue may be removed through one or more lumina.

In FIG. 27, preferred embodiments of a disc refurbisher may optionally
15 incorporate at least one tissue visualizing instrument. Optics for visualizing the treatment site—for example, at least one camera 700, mirror 710, fiber-optic bundle 720, or lens 730—may be incorporated into the energy application head. The optics may transmit human-readable visual images from the treatment site or may transmit machine-readable feedback about energy being delivered and its effect on tissue. The
20 disc refurbisher may transmit human-readable images that are displayable on a monitor or other medical imaging equipment.

At least one physical measuring instrument may be added to preferred disc refurbisher embodiments. FIG. 28 shows an exemplary instrument 740 integrated into an energy application head that may measure pressures, distances, areas, or
25 volumes with a human body. Other physical measurements may be performed by a disc refurbisher using instruments integrated or external to a disc refurbisher head.

Description of Preferred Methods

A preferred embodiment of a method of the present invention is an epidural, extradiscal, thermal treatment for repairing an injured intervertebral disc that protects vulnerable tissues near the disc and does not physically invade the disc.

- 5 Several adjacent discs may be treated by manipulating a disc refurbisher in the epidural space.

FIG. 3 shows an exemplary method of treatment. As shown, access is gained to the vertebral column through surgical means 100. An injury in or near the annulus fibrosis of an intervertebral disc is approached epidurally 110. The extent of disc injury is evaluated and the amount of energy needed to refurbish thermally the disc is calculated 120. Energy is then applied to the injured intervertebral disc from a posterior position 130. The application of energy 130 may be carried out by an instrument. FIG. 4 shows one preferred embodiment of an instrument for treating an intervertebral disc ("disc refurbisher") 200 that may be used in the preferred method.

15 The disc refurbisher is inserted epidurally from a posterior approach, remaining outside the rings of the annulus fibrosis 40 of the intervertebral disc, and is used to apply energy to an exemplary injury 50 in the annulus fibrosis 40. The amount of energy delivered in the preferred method may be monitored simultaneously with the temperature of vulnerable tissues around the disc 140. Sensors and instruments including but not limited to thermometers, thermistors, thyristors, phosphor-coated optic fibers, and temperature-sensitive crystals may monitor temperatures and pressures of delivered energy at the energy application site. Instruments such as micro-forceps, biopsy samplers, and aspirators may be inserted through a lumen in the disc refurbisher.

20 Matter and bodily tissues, such as vascular lesion tissue, sequestered disc fragments, and synovial cyst tissue may be removed through a lumen in the disc refurbisher. The amount of shrinkage and strengthening of the collagen in and around the injury is observed and evaluated to determine the intensity and duration of further energy delivery 150. The observation and evaluation of shrinkage and strengthening may be made using unaided vision. Alternately, at least one lens, mirror, camera, fiber-optic device, or other optical device may be used. Observation and evaluation could also be

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made with a mechanical probe. The mechanical success of the thermal disc refurbishment is preferably verified 160. Further energy for deadening sensory nerve endings in the annulus may be delivered to as much of the posterior annulus as is feasible or necessary to reduce discogenic pain 170. The surgical access site or sites
5 are closed. The steps may be performed in alternate order.

If the disc refurbisher used in the method has a variable thickness (such as those shown in FIGS. 7, 8, and 29-32), additional steps may also be included in the present invention. For example, there may be the step of varying the distance between the energy application region and the tissue protecting region (expanding and/or
10 contracting). This step may be performed to protect vulnerable tissues associated with the intervertebral disc. The distance may be varied in proportion to the amount of energy being delivered to the intervertebral disc. The step of varying the distance may be performed automatically or manually. In one preferred embodiment, the disc refurbisher is inserted in a contracted state and, once in place is expanded to protect
15 vulnerable tissues associated with the intervertebral disc.

The steps of sensing and monitoring may be done by gently moving the head on the exemplary injury 50 in the annulus fibrosis 40. For embodiments such as the ribbon-like epidural thermal posterior annuloplasty device shown in FIGS. 29-34, the steps of sensing and monitoring may be done with the ribbon-like epidural thermal
20 posterior annuloplasty device held still on the exemplary injury 50 in the annulus fibrosis 40.

The terms and expressions that have been employed in the foregoing specification are used as terms of description and not of limitation, and are not intended to exclude equivalents of the features shown and described or portions of them. The
25 scope of the invention is defined and limited only by the claims that follow.